U.S. Environmental Protection Agency Document Processing Desk (AMEND) Office of Pesticide Programs (7504P) 1200 Pennsylvania Ave, N.W. Washington, DC 20460

BAYER E

Attention:

Emily Schmid Product Manager, Team 25 Herbicide Branch

Subject: XtendiMax® With VaporGrip® Technology, EPA Reg. No. 264-1210; Updated Fast Track Amendment to Implement Regional Measures for 2023 Growing Season

Dear Emily Schmid,

Following discussions between Bayer CropScience LP (Bayer) and EPA regarding Bayer's September 7, 2022 fast track label amendment submission, Bayer is herein submitting an updated fast track label amendment to build on Minnesota's success in the 2022 growing season by implementing measures in eight states that are comparable to those implemented in Minnesota in 2022. As set forth below in detail, data already available indicates that Minnesota's new restrictions have led to a greater than 90% reduction in reports of apparently off-target movement in 2022, when compared to 2021. Bayer's own data also reflects this very stark reduction in Minnesota, with 2022 reports falling precipitously when compared to 2021. This fast track amendment submission follows Bayer's March 18, 2022 proposal to amend the language on Bulletins Live! Two for the XtendiMax with VaporGrip Technology (EPA Reg. No. 264-1210, Decision No. 564515) registration and both are intended to be applicable to the coming 2023 growing season.

Bayer's September 7, 2022 submission had proposed retaining the current date restriction for any applications made with hooded sprayers to provide grower flexibility. Bayer notes that several sets of peer-reviewed Bayer and academic scientific data show that applications made using hooded sprayers can effectively control dicamba off-target movement (MRID 51907701). Bayer also recognizes that EPA may require many months to review and assess this data before it would be in a position to approve the use of hooded sprayers in the label amendment. Given the rapidly approaching growing season and the fact that many growers are already making decisions about the 2023 growing season, Bayer has removed the aspect of its proposal that would have allowed applications up until current date restrictions with use of hooded sprayers. Bayer looks forward to exploring with EPA future means of encouraging use of this effective tool.

October 18, 2022

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Background

State regulators have an important role under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and are responsible for evaluating reports of pesticide misuse or reports of pesticide movement off of agricultural fields. As previously indicated¹, Bayer has spent considerable time in discussions with state authorities on dicamba issues and recognizes that most states do not believe that significant additional restrictions on dicamba use are advisable. Indeed, many states have significant concerns that additional restrictions will harm local agriculture and have also raised serious questions about whether attempting to count the number of 2021 "complaints" allegedly tallied by EPA is the best way to understand how overthe-top formulations of dicamba are actually performing in the field. Certain states have identified very specific concerns with EPA's past efforts to enumerate those complaints, in part because the numbers appear to be double-counted and do not reflect the actual cause of the complaint, suggesting that they do not reflect the state experts' actual views of what happened. All that said, Bayer has nevertheless been aggressively working to respond to EPA's concerns, and has been evaluating (as EPA has) the number of complaints received.

Each of the 34 states in which XtendiMax is registered evaluates off-target movement inquiries on an annual basis, and many states received few or no complaints in 2021 (e.g. Alabama, Arizona, Florida, Georgia, Louisiana, Maryland, Michigan, Mississippi, New York, North Carolina, Pennsylvania, South Carolina, Wisconsin). Bayer has been in the process of gathering information for 2022 from those and all other states where XtendiMax is applied as the 2022 season progresses. As in 2021, most states do not see a need to make more restrictive label amendments in 2022 either, and stress that any such decision could be harmful for growers in those states.

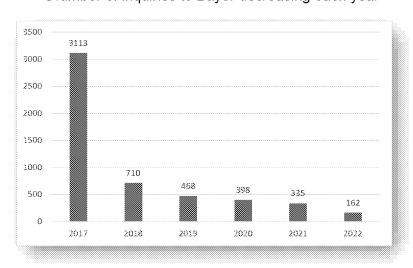
Bayer respects and, in many instances, agrees with conclusions of many state experts who cast doubt on concerns about dicamba, and believes that those state officials, charged with enforcement, have reached these conclusions based on substantial data available to them. But again, Bayer recognizes that EPA has certain questions regarding dicamba under review and notes that off-target movement inquiries have historically been concentrated in certain states.

2022 Growing Season

Following the 2021 growing season, Bayer and the other registrants of over-the-top dicamba formulations worked with the State of Minnesota and EPA on amendments to the federal label to implement Minnesota-specific restrictions to prohibit in-crop applications on soybeans by June 12th, south of I-94, and to prohibit those applications with temperatures over 85 degrees Fahrenheit. Most applications of Bayer's XtendiMax dicamba in Minnesota occurred south of I-94. A June 20th state-specific cut-off in Iowa was also incorporated in the federal label.

Bayer itself aggressively encourages reporting of off-target movement and has a program to perform investigations of those inquiries. Bayer's data indicates that the 2022 season has seen one of the lowest off-target movement inquiries nationwide. As shown in the figure below, inquiries to Bayer to date (nearly two months after the soybean over-the-top cut-off and weeks after the cotton cut-off) have been the lowest since the product was first approved for over-the-top use.

¹ April 29, 2022 Submission of Bayer CropScience Regarding Dicamba Products Registered for In-Crop Use on Soybean and Cotton.



Number of inquiries to Bayer decreasing each year

Minnesota is particularly important. For the first time in 2022, Minnesota adopted a more restrictive cut-off date and temperature threshold for over-the-top dicamba application, which applied in areas where most XtendiMax is applied. The application date restriction made applications illegal after June 12th in those areas. Predictably, this caused some number of growers not to arrange for any June dicamba applications, and instead to rely on other forms of weed control. Many other applicators in Minnesota appear to have applied on or before this date.

The data available from Minnesota and Bayer's own data show a dramatic reduction in dicamba inquiries in 2022. Minnesota data available to date shows an **at least a 90% reduction** in off-target movement inquiries compared to 2021. Although more detailed information will be available on the actual number of Minnesota dicamba applications, Bayer data available today shows that the number of XtendiMax applications remained relatively high in Minnesota this year, as inquiries declined.

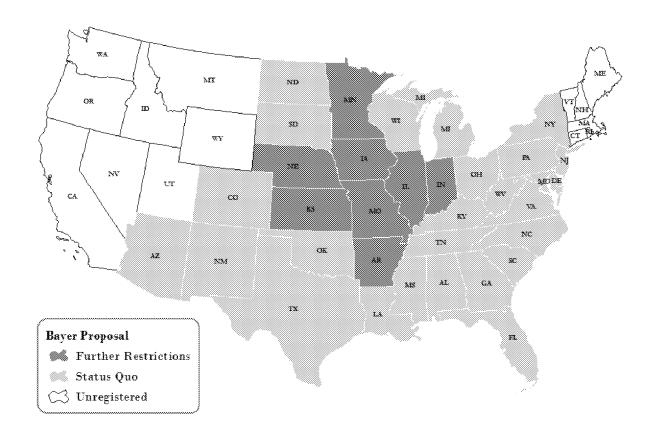
As of August 18, 2022, the total number of inquiries to Minnesota state officials was **29 for the 2022 season in comparison to 300 inquiries to Minnesota in the 2021 season**. The same significant reduction in inquiry numbers can be seen in Bayer's own data. There were **no inquiries to Bayer from Minnesota in 2022 in comparison to 68 in the 2021 season**. At the same time, preliminary Bayer data available at this point suggests that roughly 80% of the number of applications made in 2021 were again made in 2022. In other words, although the number of applications were down by perhaps 20%, the number of inquiries fell tremendously. Given that both the June 12th soybean cut-off for growing areas south of I-94 and the June 30th soybean cut-off for the rest of the state have long passed, we would not anticipate significant (if any) additional inquiries.

To be even more specific, we share the following: Multiple data sources support the conclusion that the state-specific measures adopted in Minnesota contributed to the successful 2022 growing season with at least a 90% reduction in inquiries in Minnesota; more data will follow in the coming months.

- Minnesota planting progress data from the U.S. Department of Agriculture shows that almost 90% of soybean acres statewide were planted by the June 12th cut-off south of I-94. Likewise, close to 60% were planted by late May; thus, indicating that the growers had the opportunity to use XtendiMax post-emergent in the 2022 season.
- As indicated in Table 1 in the Confidential Business Information attachment, Bayer and its distributors shipped close to 183,234 gallons of XtendiMax to Minnesota between August 2021 and June 2022 (i.e. spray season 2022), representing 86% of the gallons that were shipped to the state in 2021. A conservative assumption is that 80% of gallons in inventory will be used each season, so we assume 20% of the amount shipped in 2021 was used in the 2022 season and that 20% of the amount shipped in 2022 remains in inventory. These figures demonstrate a significant volume of XtendiMax used in Minnesota in the 2022 growing season perhaps 80% of the amount applied in 2021.

FIFRA Fast Track Amendment Proposal Going Forward

Bayer's proposed fast track amendment for the 2023 application season for over-the-top applications would build on this success in Minnesota in 2022 to incorporate additional amendments comparable to the approach taken in Minnesota that would be implemented in Arkansas (AR), Iowa (IA), Illinois (IL), Indiana (IN), Kansas (KS), Minnesota (MN), Missouri (MO), and Nebraska (NE). Specifically, Bayer proposes to reduce the cut-off of date for in-crop applications of XtendiMax in AR, IA, IL, IN, KS, MN, MO, and NE from June 30th to June 12th and also impose an additional growth stage cut-off of V4 in soybean and 1st square in cotton.

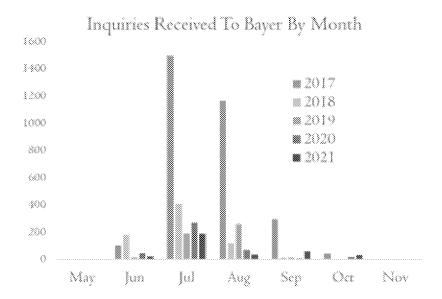


Therefore, soybean growers in these states would not apply XtendiMax after June 12th or after V4 or 1st square, whichever comes first.

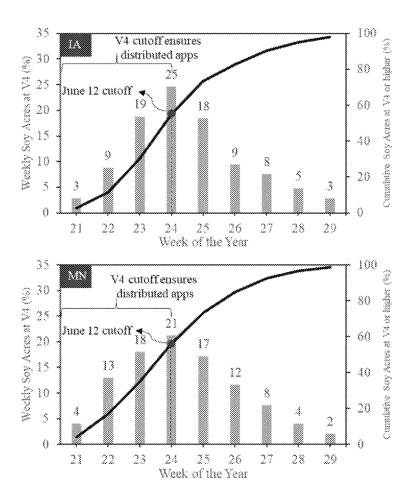
The eight states incorporated in Bayer's fast track amendment proposal account for approximately 90% percent of total off-target movement complaints to states in the last 3 years. The remaining states have few or no complaints.

Additionally, prior inquiry data below demonstrates that the majority of inquiries are not associated with early applications, supporting the proposed June 12th cut-off date in the eight states that account for 90% of the complaints to states.

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The proposed growth stage cut-off will provide an additional margin of protection by spreading out applications leading up to the June 12th cut-off, as demonstrated by the examples below that aggregate average USDA NASS data from 2016-2020. Data shows that about 40% of the dicamba-tolerant soybean will have to be sprayed several days or weeks before June 12th.



This alternative V4 growth stage restriction for soybean applications will not be new to growers as Syngenta Crop Protection, LLC's Tavium® dicamba over-the-top formulation already includes this restriction and has for many seasons.

In-crop use of dicamba is critical for U.S. soybean and cotton production—particularly in the current geopolitical environment with prospects for food shortages and continued supply chain disruptions. As a responsible company, we strive to continually support our growers and protect their interest in successful agronomy. We look forward to working with you on these important aims.

This application is being submitted electronically and contains the following:

- · This cover letter
- Application for Pesticide Registration (EPA Form 8570-1)
- Amended Master Label with changes highlighted
- Amended Master Label (clean copy)

Please contact me or George Sabbagh in our Washington D.C. office at (913) 231-6291 or george.sabbagh@bayer.com should you have any questions.

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Sincerely,

Bayer U.S. - Crop Science

Arthur Toscano

Federal Regulatory Manager

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Confidential Business Information

Table 1 CBI

Ex. 4 CBI